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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/843,159      | 04/25/2001  | Yin Luo              | A-68292-2/RMS/DHR   | 8575             |

7590 12/09/2002

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[REDACTED] EXAMINER

RAO, MANJUNATH N

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1652

DATE MAILED: 12/09/2002

1A

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                         |                     |
|------------------------------|-------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>  | <b>Applicant(s)</b> |
|                              | 09/843,159              | LUO ET AL.          |
|                              | <b>Examiner</b>         | <b>Art Unit</b>     |
|                              | Manjunath N. Rao, Ph.D. | 1652                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 October 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-37 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a method for screening for a bioactive agent capable of binding to a cell cycle protein tankyrase H, classified in class 435, subclass 4.
- II. Claim 2-3, drawn to a method for screening for agents capable of interfering with the binding of tankyrase H with p21 protein, classified in class 435, subclass 4.
- III. Claim 4-5, 7 drawn to a method for screening for a bioactive agent capable of modulating the activity of tankyrase H, classified in class 435, subclass 4.
- IV. Claim 6, drawn to a method of diagnosing cancer by determining the activity of tankyrase, classified in class 435, subclass 15.
- V. Claim 9, drawn to a method of treating an individual with a cell cycle related disorder using the inhibitor of TaHo, classified in class 514, subclass 789.
- VI. Claim11-19, drawn to polynucleotides encoding a protein, a expression vector, a host cell and a process of producing the protein, classified in class 435, subclass 69.1.
- VII. Claims 20-23, drawn to a recombinant polypeptide with SEQ ID NO:3 or 4, classified in class 435, subclass 196.
- VIII. Claims 25-26, drawn to an antibody, classified in class 530, subclass 387.5.
- IX. Claim 27-30, drawn to a method of screening for a bioactive agent capable of modulating PARP activity, classified in class 435, subclass 19.

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- X. Claims 31-34, drawn to a method of screening a candidate agent capable of inhibiting proliferation, classified in class 435, subclass 325.
- XI. Claims 35-37, drawn to a method for inhibiting growth of a tumor cell, classified in class 435, subclass 344.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through V, IX through XI are patentably distinct from each other. The method of group I drawn to screening for bioactive compounds capable of binding to tankyrase H, the method of group II drawn to screening for agents which interfere in binding to protein p21, the method of group III drawn to screening for agents which modulate the activity of tankyrase H, the method of group IV drawn to diagnosing cancer, the method of group V drawn to treating an individual with a cell cycle disorder, the method of group IX drawn to screening for bioactive agent capable of modulating PARP activity, the method of group X drawn to screening a candidate agent capable of inhibiting proliferation and the method of group XI drawn to inhibiting growth of a tumor cell are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions VI, VII, VIII are patentably distinct from each other. The polynucleotide of group VI, the polypeptide of group VII, and the antibody of group VIII, each comprise amino acid sequences and nucleotide sequences which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group VII polypeptide to regulate cell cycle versus the use of polynucleotide in a hybridization reaction, versus the use of the

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antibody in an affinity purification reaction and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

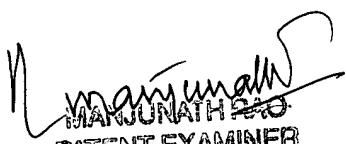
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization

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where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

  
MANJUNATH N. RAO  
PATENT EXAMINER  
Manjunath N. Rao  
December 3, 2002